

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Rosen et al. Application No.: 09/937,192 Filed: 9/21/2001 Title: Methods and Compositions for Degradation and for Inhibition of HER-Family Tyrosine Kinases Attorney Docket No.: MSK.P-038 Customer No.: 52334	Group Art Unit: 1624 Examiner: Bruck Kifle Confirmation No: 6277
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Mail Stop Patent Extension
Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Request for Reconsideration of:

PETITION TO THE DIRECTOR UNDER RULE 1.181

**For Supervisory Review of the Determination of
Patent Term Extension under 35 U.S.C. 154(b) and Rule 1.701**

Dear Sir:

Applicants hereby request reconsideration under rule 182 or 183 of the above-entitled Petition that was filed on January 10, 2007 and the subsequent Decision on Petition mailed on May 25, 2007.¹ The fee for the Request for Reconsideration as detailed under 37 C.F.R. 1.17(f) of \$400 is included herewith.

¹ Per the request issued in the Decision on Petition, Applicants have not attached copies of these papers since they are entered into PAIR.

The original Petition was dismissed in the Decision on Petition mailed to the undersigned on May 25, 2007. The cause for dismissal of the Petition was because the Legal Advisor could not find a decision of Appellate Review in favor of Applicant. The Advisor concluded, "[w]hile the Examiner was reversed on the § 112 rejections, the Examiner was affirmed on the provisional obvious double patenting rejections for all the claims. Since the Examiner has not been reversed on at least one claim for all the grounds, there is not a final decision in favor of applicants." See page 2 of the Decision on Petition. This conclusion is in error.

The provisional double patenting rejection **was never an issue** on appeal. The **only** grounds of rejection on appeal in this case were the 35 USC 112 rejections.² The Examiner acknowledged the same in the Examiner's Answer concluding that the "appellant's statement of the grounds of rejection to be reviewed on appeal is correct."³ However, to Applicants' frustration as noted in their Reply Brief, the Examiner seemingly 'cut and paste' his previous office action into the Examiner's Answer whereby the provisional double patenting rejections (among additional mischaracterized rejections) were inadvertently added to the Answer even though they were never at issue in the Appeal.⁴

Even if the provisional double patenting rejection were an issue in the appeal, which it was not, Applicants can find nowhere where the Examiner has to be reversed, "on at least one claim for all the grounds" to find a decision in favor of Applicants, as asserted in the Decision on Petition. Applicants request that the basis for this requirement be identified if the petition is not granted.

² See Exhibit A: An excerpt from the Applicants' (September 22, 2005) Appeal Brief listing the "Grounds of Rejection to be Reviewed on Appeal".

³ See Exhibit B: An excerpt from the (December 12, 2005) Examiner's Answer indicating that Applicants' listing of the "Grounds of Rejection to be Reviewed on Appeal" **were correct**.

⁴ See Exhibit C: An excerpt from the Applicants' (February 13, 2006) Reply Brief demonstrating that the Examiner "cut and paste" mischaracterized rejections from his last office action into the Examiner's Answer.

The applicable law (i.e. 35 U.S.C. 154(b)(2)) states that patent term extension is available, "[i]f the issue of a patent is delayed due to appellate review by the Board of Patent Appeals and Interferences or by a Federal court and the patent is issued pursuant to a decision in the review reversing an adverse determination of patentability...". The BPAI reversed **all** of the Examiner's 112 rejections and the case proceeded straight to allowance and no terminal disclaimer was filed. In other words, the only determination adverse to patentability was reversed. The double patenting rejection was a provisional rejection and could not mature to an actual basis for rejection until such time as the cited application matured to a patent. This has still not happened. Thus the decision on petition penalizes Applicants for failing to prevail on an issue that was never argued, that was never contested, and that was never real.

Applicants request that upon reconsideration of the Petition a finding be made that (1) there was a final decision in favor of Applicant and (2) that a period of patent term extension be awarded as described in the original Petition, or a suspension of any rule that may make the provisional rejection an issue so that Applicants are granted the extension to which they are in fairness entitled.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Marina T. Larson", written over a horizontal line.

Marina T. Larson, Ph.D

Reg. No. 32,038

Ryan E. Anderson

Reg. No. 51,405

Attorneys for Applicant(s)

(970) 262 1800

★ Grounds of Rejection to be reviewed on Appeal

Claims 3, 4, 6 and 9-34 stand rejected under 35 USC § 112, first paragraph, as lacking enablement.

Claims 3, 4, 6 and 9-34 stand rejected under 35 USC § 112, second paragraph, as indefinite.

Argument

I. The Enablement Rejection

Claims 3, 4, 6 and 9-34 stand rejected for lack of enablement. In making this rejection, the Examiner has paid no attention to the scope of the individual claims or the arguments presented, but has treated all claims as a group. This is improper, since the rejection plainly cannot apply to all of the mentioned claims.

A. Claims 10 and 11 are composition claims within the scope said to be enabled.

The Examiner acknowledges that the present specification is enabling for the "geldanamycin dimer, wherein the linker is $-(CH_2)_{4-12}$ and bonded to the 17-carbon of each geldanamycin, to treat breast cancer." (Office Action, page 2). Given this acknowledgment, the rejection of claims 10 and 11, which are compositions claims (and therefore not dependent on any particular use) and which specifically fall within the scope that the Examiner says are enabled, is clearly in error and suggests that the Examiner has failed to give due consideration to the claims and the application.

The Examiner also asserts a lack of enablement without identifying the claims rejected on this ground because "the specification does not provide enablement for the treatment of cancer generally." This ground for rejection cannot be applied to composition claims.

Accordingly, the rejection under 35 USC § 112, first paragraph, for lack of enablement should be reversed with respect to claims 10 and 11.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal. Co-pending Application 09/960,665, however, is drawn to similar subject matter.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

No amendment after final has been filed. This appeal brief was filed before a final rejection.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

No evidence is relied upon by the examiner in the rejection of the claims under appeal.

Ex. B

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Applicant(s): Rosen	
Application No.: 09/937,192	
Filed: 9/21/2001	Group Art Unit: 1624
Title: Methods and Compositions for Degradation and for Inhibition of HER-Family Tyrosine Kinases	Examiner: Bruck Kifle
Attorney Docket No.: MSK.P-038	

REPLY BRIEF FOR APPELLANT

This Reply Brief is filed in support of Applicants' Appeal from the rejection mailed July 11, 2005, and in response to the Examiner's Answer mailed December 12, 2005.

In the Examiner's Answer (Page 1), the Examiner states that "no evidence is relied upon by the examiner in the rejection of the claims under appeal." However, on page 5 of the Examiner's Answer he refers to a paper of Sreedhar et al. This paper is not of record in this case, and this part of the Examiner's Answer should be stricken.

★ It is noted with some frustration that the Examiner's Answer is essentially a reprint of prior actions, even to the point of identifying a "new ground for rejection" on Page 7. This same "new grounds for rejection" appeared in the Official Action mailed July 11, 2005, and was therefore addressed in the original appeal brief. More significantly, the Examiner has provided little or no meaningful response to the arguments made in the Appeal Brief, and has maintained the same generalized positions as before.

The Examiner's Answer states that "claims 3, 4, 6 and 9-11 are not rejected for lack of enablement." (page 9) Since these claims were rejected in the final Office Action, it is understood by

Ex. C

- 1 -

REPORTING LETTER _____
COMPUTER DOCKET _____
PAPER DOCKET None needed.